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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,997	06/21/2007	Eric James Wall	CHM-022M	8939

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EXAMINER	
PRICE, NATHAN R	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,997	WALL ET AL.	
	Examiner	Art Unit	
	NATHAN R. PRICE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2009 has been entered.

Response to Amendment

2. This office action is responsive to the amendment filed on November 10, 2009. As directed by the amendment: claims 1, 3, 9, 10, 16, and 17 have been amended, claims 12-15 have been cancelled, and 18-22 have been added. Thus, claims 1-11 and 16-22 are presently pending in this application.

Claim Objections

3. Claims 5, 6, 10, 17, 21 are objected to because of the following informalities: “the means for separably affixing” (claims 5, 6) lacks antecedent basis; “the retracting means” (claims 10 and 21) lacks antecedent basis; “the needle retraction means” (claim 21) lacks antecedent basis; “the injection means" (claim 17) lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 1, 7, and 20, the limitation “comprising an adhesive on a skin-facing surface thereof *and an opposed surface*", it is unclear whether the "opposed surface” of claim 1 and 7 is a surface opposed to the adhesive surface that also comprises an adhesive, or an element of the separable base.

7. Regarding claim 19, the limitation “the at least one engaging member cannot be biased to its second position unless the needle is at its housing position" is indefinite as it lacks antecedent basis in claims 18 and 1, and it is unclear from these claims what “second position” and “housing position” comprise. It may be necessary to amend claim 18 to depend on claim 6. Furthermore, "housing position" should be amended to "position within the housing".

8. Regarding claims 1, 17, and 20, claim element “means for injecting a vaccine from the reservoir through the needle” is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. First, the means for language of the claim is not reflected in the specification. Furthermore, Par. 00101 appears to describe an injecting means, but it is unclear exactly which elements embody the injecting means.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

9. Regarding claims 1 and 20, claim element "means for separably affixing the separable base with the base portion" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Turning to the specification, no structure is recited for this means. Par. 00102-00103 recite structure for a base securement means, and par. 00123 describes structure for base separating means, but it is unclear whether these descriptions are the intended structure.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

10. Regarding claims 1 and 22, claim element “base separation means for selectively separating the separable base from the device while the separable base is secured to the skin” is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Par. 00104 and 00123 appear to describe a base separation means, but it is unclear which elements referenced are encompassed by this means. Furthermore, the claimed "means" does not reflect the language used in the specification ("...for selectively separating the separable base..."). Finally, claims 5-11 seem to contradict the disclosure of the specification, claiming the structure described in par. 00104 and par. 00123 of the specification as “means for separably affixing”.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

11. Regarding claims 9, 10, 18, 20, and 21, claim element "a means for retracting the injection needle" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The specification does not appear to specifically reference a means for retracting the injection needle or define what structure is encompassed by this limitation.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

12. Regarding claim 10, claim element "means for moving a needle insertion securement from a first position that secures the needle in its extended position to a second position that does not secure the needle in its extended position" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The specification does not appear to specifically reference a means as defined by this limitation or define what structure is encompassed by this limitation.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

13. Claims 2-6, 8, 11, and 16 are rejected under this statute as depending on a rejected base claim.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 2, 4-6, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627).

16. Regarding claims 1, 2, 4-6, 16, and 18-22, Miskinyar discloses an injection device for self-administering vaccine injections to a patient (fig. 7-9), comprising: a housing 10 having a base portion (comprising 118 and 120); a needle 94 positioned within the housing having an injection end and an outside diameter, configured for extension to a position wherein the injection end extends through and beyond the base portion (see fig. 9); means for injecting a vaccine from the reservoir through the needle (spring 128); a separable base 90 associated with the base portion, comprising an adhesive (underneath layer 130) that secures the device to the skin of a patient during the time that the device self-administers the injection of the vaccine to the patient; a means for separably affixing the separable base with the base portion 108 and a base separation means 116 for selectively separating the separable base from the device while the separable base is secured to the skin (see fig. 8, 116 separates 128 from 90); the separable base can be reaffixed to the base portion after separation (removal of 116; see fig. 9); the means for separably affixing comprises at least one engagement in the opposed surface of the separable base (engagement formed by right angle between

86 and 84, fig. 8) and at least one engaging member 120 extending from the base portion of the housing; wherein the at least one engaging member has a first position associated with engagement wherein the removable base is secured to the housing (fig. 9) and a second position associated with the engagement wherein the removable base is not secured to the housing (fig. 8); means for retracting the injection needle 102.

17. Miskinyar fails to disclose the injection end of the needle having an outside diameter greater than .2 mm and less than about .38 mm. However, Woehr et al. teaches such needle diameter (see table 1, page 5, which specifically mentions needle outer diameters of .3 mm, .33 mm, and .35 mm). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar apparatus as taught by Woehr et al. for the purpose of providing a needle sufficiently sized diameter to require an appropriate application of strength for use (par. 0079, table 1).

18. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Hunn et al. (US 20040158207).

19. Regarding claims 3 and 4, Miskinyar fails to disclose an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof and extending from the entire periphery of the separable base. However, Hunn et al. teaches an adhesive flap 2 (fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar apparatus as taught by Hunn et al. for the purpose of improving the adhesion

of the device to the injection site by increasing the surface area coated with adhesive (see fig. 1).

Response to Arguments

20. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763